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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,004	12/15/2003	Yi Feng Zheng	7459	2953

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EXAMINER	
HAQ, SHAFIQUL	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,004	ZHENG ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/1/05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6,13-25,27,30 and 31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6,13-25,27,30 and 31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/11/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

10

DETAILED ACTION

1. Applicants' responses and amendments filed July 01, 2005 is acknowledged and entered.

2. Claims 7-12, 26, 28-29 and 32 have been cancelled.

3. Claims 1-6 and 13-25, 27 and 30-31 are pending and under active prosecution.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Pouletty et al (US 2003/0171435 A1).

Claims recite compound of formula I, immunogen and antibody against the compound..

Pouletty et al. disclose amphetamine derivatives, immunogen and antibodies against them (see title and abstract). Pouletty et al. disclose several amphetamine derivatives and at least one of them anticipates the compound of formula I of the present invention. As for example, compare formula I of present invention with immunogen 12 (claim 17 of page 16) of the reference. Immunogen 12 wherein R_3, R_4, R_7=H; R_1, R_2=H or C_1-C_3 alkyl ; R_6=OR_9 wherein R_9=H or C_1-C_3 alkyl and R_{11}= -

$O(CH_2)_m$- wherein m=1-4, anticipates formula I of claim 1 of the present invention. Also, note that R_{11} (i.e. - $O(CH_2)_m$-) can be linked to a carrier (claim 17) or can have a functional group such as SH (see claim 1 wherein R_{10}=thiol).

Pouletty et al. also disclose that the carrier can be a polyamino acid or a protein (e.g. albumin, ovalbumin, KHL or a peptide fragment) to be used as an immunogen (claim 19). Furthermore, antibodies against the immunogens are also disclosed (see claims 23-27).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 6, 13-25, 27 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hui et al. (EP 1340981 A2) in view of Pouletty et al (US 2003/0171435 A1).

Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

Hui et al. disclose a methods/assays and a kit for detection and quantitative determination of amphetamine derivatives (paragraphs 0012, 0029, 0064-0067, 0059 and 0060) using antibody against amphetamine derivatives and label

derivatives (such as fluorescent, luminescent, radioactive isotope etc.) (paragraph 0022).

Hui's amphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, the linking group or the position of linker at the amphetamine derivative is different from the present compound.

Pouletty et al. disclose amphetamine immunogen and antibodies (see title and abstract) and disclose several amphetamine derivatives as described in paragraph 5 above and at least one of them is the same as the compound of formula I of the present invention.

Sine detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody is available, one would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug.

Therefore, given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Pouletty et al in the method of Hui et al, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives..

8. Claims 6, 13-25, 27 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rouhani et al. (GB 2361473 A) in view of Pouletty et al (US 2003/0171435 A1).

Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

Rouhani et al. disclose a method for detection of ecstasy-class analogs. Rouhani discloses preparation of antibody (page 6, lines 19-24; pages 16-18) using the compound conjugated with carrier protein (see abstract) and different homogeneous and heterogeneous immunoassay methods (pages 8-9 and 34) and assay kit (page 31, lines 9-12 and claim 10) for detection and quantitation of ecstasy-class analogs in biological samples (page 22, lines19-24). Rouhani also discloses the above compound conjugated with a protein to be adapted as immunogen (page 41, example 7). Attachment to a carrier protein or a label is also inherent in the process of immunization (see claims 7 and 8) and immunoassay methods (see pages 8-9 and 34) as disclosed in this reference.

Rouhani's amphetamine and methamphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, the linking group or the position of linker at the amphetamine derivative is different from the present compound.

Pouletty et al. disclose amphetamine immunogen and antibodies (see title and abstract) and disclose several amphetamine derivatives as described in paragraph 5

above and at least one of them is the same as the compound of formula I of the present invention.

Sine detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody is available, one would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug.

Therefore, given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Pouletty et al in the method of Rouhani et al, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHAFIQUL HAQ
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ART UNIT 1641

MARY E. CEPERLEY
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